

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

JONATHAN A. BLOOM,)	
)	
Plaintiff,)	
)	
v.)	Civil No. 5:16-cv-121
)	
SYLVIA M. BURWELL,)	
Secretary of the U.S. Department)	
of Health and Human Services,)	
)	
Defendant.)	

SECRETARY’S REPLY
IN SUPPORT OF MOTION FOR SENTENCE SIX REMAND

I. INTRODUCTION

Defendant Sylvia M. Burwell, Secretary of the United States Department of Health and Human Services (“the Secretary”), files this memorandum in reply to Plaintiff’s Opposition to the Secretary’s Motion for Remand. Plaintiff, Jonathan Bloom, has brought this action pursuant to the Social Security Act, 42 U.S.C. § 405(g), and the Medicare Act, 42 U.S.C. § 1395ff(b)(1)(A), to challenge a decision by the Medicare Appeals Council (“MAC” or “Council”) denying Plaintiff’s request for Medicare coverage of a transmitter and disposable sensors for a continuous glucose monitor (“CGM”) system. Plaintiff’s arguments ignore important aspects of administrative law under 42 U.S.C. § 405(g) and coverage requirements under the Medicare program, in an attempt to demonstrate that a remand in this case will only result in further delays for Plaintiff. These arguments do not undermine the Secretary’s position that remand pursuant to the sixth sentence of 42 U.S.C. § 405(g) in this case is supported by adequate good cause, and will promote principles of judicial economy.

II. ARGUMENT

A. The Secretary Has Demonstrated The Existence Of Good Cause For A Remand Pursuant To The Sixth Sentence Of 42 U.S.C. § 405(g).

Review of the administrative decision regarding Plaintiff's claims for Medicare coverage is authorized by 42 U.S.C. § 405(g), and this statutory framework is the exclusive authority for review of such claims. *See* 42 U.S.C. § 1395ff(b)(1); 42 U.S.C. § 405(h); *Heckler v. Ringer*, 466 U.S. 602, 605 (1984); *Abbey v. Sullivan*, 978 F.2d 37, 43 (2d Cir. 1992). In the sixth sentence of 42 U.S.C. § 405(g), Congress expressly provided a means for "the district court to remand without making any substantive ruling as to the correctness of the [Secretary's] decision . . . [,]" *Raitport v. Callahan*, 183 F.3d 101, 104 (2d Cir. 1999), where, relevant here, the Secretary is able to demonstrate the existence of "good cause" prior to answering the complaint. 42 U.S.C. § 405(g). *See also Longey v. Sullivan*, 812 F. Supp. 453, 455 (D. Vt. 1993) (explaining that "[s]entence six remands . . . are granted only upon motion of the Secretary for good cause prior to any answer of the plaintiff's complaint.").¹ Good cause for this type of remand exists (and is "the proper course, except in rare circumstances," according to the Supreme Court) where the decision being challenged contains a legal error, or where the administrative record is unclear. *See Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985); *see also Palisades Gen. Hosp., Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005) ("[U]nder settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with correct legal standard." (internal quotation marks and citation omitted)).²

¹ Sentence six remands before answer are also permitted on the basis of newly discovered evidence, however, that is not the basis for the Secretary's request for remand in this case.

² Plaintiff criticizes the Secretary's reliance on "cases relating to a fourth sentence remand under 42 [U.S.C.] § 405(g)," and in particular, the citation to the Second Circuit's decision in *Rosa v. Callahan*, 168 F.3d 72 (2d Cir. 1999). Pl.'s Br. 5 n.4. However, the Secretary did not cite directly to the *Rosa* decision, but instead to *Botta v.*

The current case presents the type of circumstances described above and, therefore, a remand to the Secretary is “the proper course” for the litigation. First, given the concerns regarding the MAC’s treatment of Policy Article A33614, as described in the Secretary’s motion and in Plaintiff’s Complaint, there is good cause for remanding the case to ensure the determination on Plaintiff’s benefit claim accords with the applicable statutes and regulations. *Accord Roderick L. Bremby, Commissioner v. Burwell*, No. 3:15-cv-1397 (D. Conn. Apr. 29, 2016) (“At this point the Secretary has not acknowledged legal error in the MAC final decision . . . [However,] the Court views the Secretary’s [representations] as an acknowledgment that there is a legitimate question as to whether the MAC applied the correct standard in deciding the plaintiff’s case The Court recognizes that the Secretary has a legitimate interest in ensuring that all arguments are given full consideration and that the correct legal standard is utilized in connection with Medicare payment decisions.”).

On that point, it is important to note that Plaintiff specifically alleges in Count IV of his Complaint (¶¶ 129-133) that the Secretary improperly deferred to the Policy Article. In his opposition to the Secretary’s motion for remand, Plaintiff now contends that “remanding the case back to the MAC will serve no purpose” because “the MAC did not base its decision[] on deference to the Policy Article,” Pl.’s Br. 9-10. Despite this new position, Plaintiff nonetheless concedes that the MAC ultimately found “no reason to depart from the ‘guidance’ afforded by the [Policy] Article” even though “[the] arguments [contained in the Policy Article] . . . are without support in the administrative record.” *Id.* Consequently, while not expressly so stating, it does appear that the MAC’s decision “incorporate[d] a false premise: that this Policy Article,

Barnhart, 475 F. Supp.2d 174 (E.D.N.Y. 2007), a case involving a sixth sentence remand that relied on *Rosa*. See *Botta*, 475 F. Supp.2d at 186, 189. In any event, the Supreme Court has noted that the “[i]mmediate entry of judgment . . . is in fact the principal feature that distinguishes a sentence-four remand from a sentence-six remand,” *Shalala v. Schaefer*, 509 U.S. 292, 297 (1993), as opposed to the reasoning behind a court’s decision to remand in either particular situation. See, e.g., *Melkonyan v. Sullivan*, 501 U.S. 89, 99 (1991) (discussing whether the district court remanded pursuant to sentence four or sentence six of 42 U.S.C. § 405(g)).

like a Local Coverage Determination, was entitled to ‘substantial deference’” *Finigan v. Burwell*, C.A. No. 15-12246-WGY, 2016 WL 2930905, 2016 WL 2930905, at *6 (D. Mass. May 19, 2016). Affording LCD-type deference to a Policy Article is legal error and, as Plaintiff concedes, it appears that the MAC did just that. Given the existence of this apparent shortcoming in the MAC’s decision, there is good cause for a remand before answer pursuant to the sixth sentence of 42 U.S.C. § 405(g). *See Fla. Power & Light Co.*, 470 U.S. at 744 (“If the record before the agency does not support the agency action, . . . or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course . . . is to remand to the agency for additional investigation or explanation.”); *Finigan*, 2016 WL 2930905, at *5, *7 (remanding for further record development on whether a CGM system is DME); *see also* Compl. ¶¶ 105-108 (asserting that the MAC rendered its decision “[w]ithout support”).

Plaintiff, thus, also concedes that the administrative record is unclear as to whether a CGM qualifies as DME and this lack of clarity provides additional good cause for a sentence six remand before answer. *See Fla. Power & Light Co.*, 470 U.S. at 744; *see also Torres v. Shalala*, 938 F. Supp.211, 217-18 (S.D.N.Y. 1996) (citing cases, including for proposition that failure to develop a full and fair record constitutes good cause). Plaintiff alleges that the record lacks evidence³ pertaining to the functionality of a CGM system and whether it qualifies as DME, Pl.’s Br. 9-10. Moreover, other courts, after briefing and evaluating the merits of CGM coverage

³ The Secretary should not be prohibited from making the argument that further record development is needed in this case (or be otherwise penalized) because she did not participate during the administrative proceedings, which Plaintiff suggests. *See* Pl.’s Br. 9. While an Administrative Law Judge (“ALJ”) may request information from the Medicare contractor and call Medicare contractor or CMS personnel as witnesses, *see* 42 C.F.R. § 405.1010, something that was not done during the ALJ proceedings in this case, proceedings involving beneficiary claims under Medicare Parts A and B are typically non-adversarial. *See* 42 C.F.R. §§ 405.1008 and 405.1012. In particular, CMS or the Medicare contractor may not participate in an ALJ hearing where, as here, a beneficiary is unrepresented. 42 C.F.R. § 405.1012(a). Plaintiff was unrepresented during the proceedings below. *See* Exhibit A at 5 (noting that Plaintiff “was seeking representation from the Legal Aid clinic, before he undertook this appeal on his own”).

requests where the administrative record was similarly lacking in such evidence, have ordered remands to the Secretary for further proceedings. *See Finigan*, 2016 WL 2930905, at *5, *7 (remanding for further record development on whether a CGM system is DME); *Whitcomb v. Burwell*, C.A. No. 13-CV-990, 2015 WL 3397697, at *4 (E.D. Wis. May 26, 2015)(remanding to the Secretary to address “the question . . . whether a continuous glucose monitor is reasonable and necessary for Whitcomb *and not otherwise excluded*,” and “to permit the Secretary to assess th[e] case under the proper legal standard” (emphasis added)). Here, the Secretary acknowledges the outcomes in those cases and, rather than pursuing litigation that is likely to result in a remand for further proceedings, asks this Court to remand the case before answer. The existence of these precedents resulting in remand for further proceedings under similar circumstances presented here further establishes good cause for remand before answer.

While a remand to the MAC will necessarily entail further record development on the basis for the benefit category language contained in Policy Article A33614, that does not mean, as Plaintiff suggests, *see* Pl.’s Br. 10, that an administrative decisionmaker will ultimately reach the same outcome after considering new evidence—including new evidence submitted by Plaintiff. *See, e.g., Vasquez v. Sec’y of Health & Human Servs.*, 632 F. Supp. 1560, 1565 (S.D.N.Y. 1986). And critically, Plaintiff continues to “bear[] the burden of proving entitlement to Medicare coverage,” *Keefe v. Shalala*, 71 F.3d 1060, 1062 (2d Cir. 1995), which includes demonstrating that the requested item or service fits within a statutorily defined Medicare benefit category. 42 U.S.C. §§ 1395k (scope of benefits under Medicare Part B), 1395x (definition of medical and other health services), 1395y(a)(1)(A) and (B) (reasonable and necessary); *see also* Medicare Program; Notice of Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55, 634, 55,635 (Sept. 26, 2003). If the Secretary’s motion for

remand is granted, Plaintiff will have the further opportunity to meet his burden of proof and submit evidence supporting his position, thereby strengthening his argument before the Secretary, and if necessary, upon return to this Court for further action on the Complaint.

If there is any doubt about whether these issues with Secretary's decision demonstrate good cause for sentence six remand before answer, "due deference" should be given to the Secretary's judgment on the matter. *Doctors Nursing & Rehab. Ctr. v. Sebelius*, 613 F.3d 672, 681 (7th Cir. 2010). Going forward on the merits, with a record that all parties recognize is deficient, will merely delay a final decision for Plaintiff since remand to the Secretary for the reasons stated herein is the most likely outcome after litigation on the merits. As noted, the decisions remanding the *Finigan* and *Whitcomb* cases to the Secretary under very similar facts provide significant support for the likelihood of remand after litigations. Rather than waiting several more months for briefing on the merits and a decision from the Court, the Secretary genuinely seeks to speed the process and take the case back at this stage, prior to answer, for further administrative action.

B. Plaintiff's Remaining Arguments Do Not Undermine The Secretary's Showing Of Good Cause In This Case.

Plaintiff's arguments contesting remand are primarily predicated on a critique of the Medicare program and the claims appeal process, and extend beyond the current matter. While the Secretary acknowledges that Plaintiff has taken "many cases through the Medicare appeals process," Pl.'s Br. 10, Plaintiff's prior successes have no relevance to the instant case, and this argument ignores the confines of the Medicare program.⁴ Medicare is a statutorily

⁴Plaintiff refers to earlier, successful appeals regarding other similar claims and suggests that the Secretary erred in her characterization of the administrative proceedings in the case presently before the Court. Pl Br. 6, fn. 5. In her Motion for Remand, the Secretary accurately described the administrative proceedings *is this case*. See Exhibit A pp. 1-4 (Plaintiff's claims for coverage of disposable CGM sensors furnished on March 19, 2014 and June 18, 2014 and a CGM transmitter furnished on June 24, 2014 were denied at all levels).

defined benefit program and, as a result, “does not require coverage for all medically necessary procedures” and items. *Goodman v. Sullivan*, 891 F.2d 449, 450 (2d Cir. 1989).

Moreover, while the Medicare appeals process may, according to Plaintiff, be lengthy at times (the “administrative system . . . processes literally millions of claims every year”), it is nonetheless the review process specifically mandated by Congress to ensure compliance with Medicare program requirements. *Heckler v. Ringer*, 466 U.S. 602, 672 (1984) (also noting that “Congress must have felt that cases of individual hardship resulting from delays in the administrative process had to be balanced against the potential for . . . premature judicial intervention” in the form of advisory opinions regarding whether a particular item or service could be covered); *see* Omnibus Budget Reconciliation Act of 1986, Pub.L. No. 99–509, § 9341, 100 Stat. 1874, 2037–38 (1986) (codified at 42 U.S.C. § 1395ff) (extending the same review to Part B claims); *Isaacs v. Bowen*, 865 F.2d 486, 476-77 (2d Cir. 1989) (finding that the administrative review process for Part B claims did not deprive Medicare beneficiaries of due process despite their argument of unreasonable delay). Although the Second Circuit in *Isaacs* did indicate that “delay can be so unreasonable as to deny due process[] . . . when it is inordinately long or when a recipient demonstrates immediate financial need,” neither of those factors appears to be present here.⁵ *Id.* at 477 (also finding “the estimated total of 19 months from claim initiation to completion of ALJ review [non]remarkable in the Medicare . . . system[]”). In short, Plaintiff’s characterizations of the Medicare claims review process do not provide a basis for undermining the Secretary’s request for remand given the parties’ undisputed

⁵ The Secretary notes that some delays during the ALJ proceedings were due to Plaintiff’s own schedule. *See* Exhibit A at 4-5. And Plaintiff does not assert that the time needed for remand would cause a financial hardship or an inability to procure and use the CGM device and supplies.

concerns about the MAC's decision and the administrative record here. *See Florida Power & Light Co.*, 470 U.S. at 744.⁶

The Secretary also emphasizes that Plaintiff has pursued this case through the Medicare beneficiary claims appeal process, not as a challenge to any policy. *See* 42 U.S.C. § 1395ff(a) and (b); 42 C.F.R. Part 405, Subpart I. In this process, Plaintiff disputes only the application of relevant Medicare rules, regulations, or policies to his particular coverage request. *See* 42 U.S.C. § 1395ff(b) (citing 42 U.S.C. § 405(b) and (g)). As a result, this case is not an appropriate vehicle to challenge policy decisions of the administrative contractor or the Secretary. Therefore, Plaintiff's argument that "the MAC has indicated that it intends to continue to apply the Article when denying claims for Medicare beneficiaries," Pl.'s Br. 10, is not an issue properly before this Court. Consequently, the MAC's alleged action in other cases is simply not relevant to the ultimate determination of Plaintiff's benefit claim here.⁷

Finally, as the Secretary explained above and in her motion, a remand at this stage of the litigation would likely result in a swifter decision for Plaintiff. Not only has remand been the result in recently litigated cases involving CGM coverage requests, but the Medicare regulations in fact allow ALJs to issue final decisions following remand by a Federal district court. *See, e.g.*, 42 C.F.R. § 405.1140. In addition, the Secretary would not object to providing status updates to this Court on the progress of Plaintiff's case—and indeed, there is nothing to prohibit the Court

⁶ The fact that other ALJs in the Medicare claims appeal process have ruled in favor of Plaintiff in the past also does not mean Plaintiff is entitled to Medicare coverage for his CGM and related supplies. *See* Pl.'s Br. 10. In particular, the applicable regulations specifically state that ALJ decisions that do not adhere to policy guidance, for instance, the manual instructions and program memoranda discussed in the Secretary's motion, are not precedential. 42 C.F.R. § 405.1062(b).

⁷ For similar reasons, Plaintiff's reliance on *In re: Local Coverage Determination Complaint: Glucose Monitors (L11530/L33822 and Local Coverage Articles A33614/A52464)*, DAB ALJ Decision No. CR4596, 2016 WL 2851236 (Apr. 29, 2016), appeal filed Board Docket No. A-16-96 (May 23, 2016), is misplaced, as that case involves a challenge made under 42 C.F.R. Part 426. *See* Pl.'s Br. 6-7. Given that these cases present different issues and are grounded in different statutory and regulatory authorities, Plaintiff cannot argue that any decision in that ongoing litigation supports the notion that the Secretary acted unreasonably here.

from crafting a remand order that further addresses Plaintiff's concerns regarding timing and case management.

III. CONCLUSION

For the foregoing reasons and those previously addressed in the Secretary's Motion for Remand, the Secretary respectfully requests that the Court remand this case pursuant to the sixth sentence of 42 U.S.C. § 405(g) for further administrative proceedings.

Dated at Burlington, in the District of Vermont this 12th day of September, 2016.

Respectfully submitted,

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